

# Ozurdex™ (dexamethasone intravitreal implant) 0.7mg

FDA-approved drug treatment for macular edema following branch or central retinal vein occlusion.

### To learn more:

Visit [www.Ozurdex.com](http://www.Ozurdex.com) for a wealth of information about retinal vein occlusion and treatment with OZURDEX™ intravitreal implants. You'll also find links to other valuable online resources.

**Please see Important Safety Information on pages 12-13.**

**Full prescribing information has been provided to your doctor.**

# A Dexciting Advance

A Novel Dexamethasone Intravitreal Implant

# Ozurdex™ (dexamethasone intravitreal implant) 0.7mg

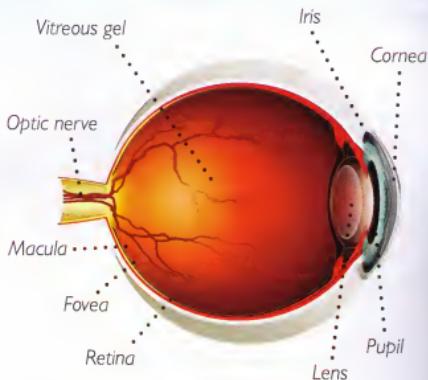
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# Your eyes:

# A Look Inside

## What makes up the eye?



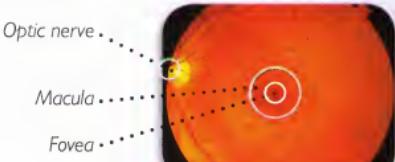
## How does the eye work?

Light enters through the cornea, passes through the opening in the iris, called the pupil, and then to the lens which focuses light on the retina—the inner lining of the back of the eye. The retina is lined with light-sensitive cells, or photoreceptors, called rods and cones. The macula is the center of the retina, and it is responsible for sharp central vision. The fovea is a small depression in the macula that provides the sharpest vision of all. When light reaches the retina, the photoreceptors send impulses along the optic nerve to the brain, which interprets them as vision.

## Why is a healthy retina important?

A healthy retina is essential for normal vision. A number of diseases can damage the retina, which may lead to impaired vision or loss of vision. One of these diseases is retinal vein occlusion, which occurs more commonly as people reach middle age.

A photograph (called fundoscopy) of a healthy retina.



*Image from the National Eye Institute online archive.*

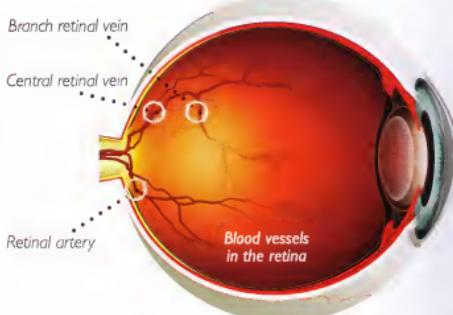
# Your condition:

# RETINAL VEIN OCCLUSION

## What is retinal vein occlusion?

Blood circulating through the retina leaves the eye by draining into the retinal vein. A retinal vein occlusion is a blockage that prevents normal blood flow out of the eye. The blockage may be caused by a blood clot, by compression (squeezing) from a nearby retinal artery, or by diseases that affect the blood vessels, such as diabetes, glaucoma, high blood pressure, and atherosclerosis (hardening of the arteries).

There are 2 main types of retinal vein occlusion: branch retinal vein occlusion (BRVO) and central retinal vein occlusion (CRVO). In BRVO, the blockage occurs in one of the smaller branch vessels that connect to the central retinal vein. In CRVO, the blockage occurs in the central retinal vein, which is the main drainage line for blood leaving the retina.



## What are the symptoms of retinal vein occlusion?

Sudden blurring or vision loss in all or part of one eye are the most common symptoms of retinal vein occlusion. For some patients, the vision loss may happen gradually over a period of days or weeks instead of suddenly. The amount of blurring or vision loss depends on how much damage to the retina has occurred.

## How does retinal vein occlusion affect the eye?

The blockage of blood flow can cause retinal bleeding, damage nearby capillaries (small blood vessels), and deprive the retina of oxygen. When retinal capillaries are damaged, it can lead to swelling of the retina (known as edema). If the edema affects the central part of the retina, called the macula, it can reduce your central vision. In addition, low oxygen levels may trigger the formation of fragile new blood vessels that can also cause vision problems. Untreated retinal vein occlusion can take months to heal and lead to permanent vision impairment in the affected eye.



BRVO



CRVO

Images of retinal vein occlusions.

# Your treatment:

## OZURDEX™ (dexamethasone intravitreal implant) 0.7mg

### Why did my doctor choose OZURDEX™?

OZURDEX™ has been approved by the US Food and Drug Administration (FDA) to reduce macular edema following branch or central retinal vein occlusion. OZURDEX™ has been proven effective in large clinical trials. If you are to receive an OZURDEX™ intravitreal implant, it means you have a retinal vein occlusion that is causing macular edema. Your doctor has chosen OZURDEX™ to help restore your vision. He or she will discuss more specific reasons why OZURDEX™ was selected as well as the benefits and risks of treatment.

### How does the OZURDEX™ intravitreal implant work?

OZURDEX™ is a biodegradable implant containing the corticosteroid dexamethasone. Corticosteroids such as dexamethasone block chemical pathways that lead to inflammation, leakage from the retinal blood vessels, and edema. By reducing macular edema, OZURDEX™ can help reverse some vision loss that may be caused by a retinal vein occlusion.

### What is a biodegradable implant?

A biodegradable implant is one that doesn't need to be removed after it's done working. OZURDEX™ biodegradable implants use advanced

NOVADUR™ drug delivery technology, in which biodegradable material is combined with the active drug dexamethasone to form a tiny rod-shaped implant. Inside the eye, the implant is slowly dissolved by the vitreous gel that fills the eye, releasing dexamethasone over a period of months.

OZURDEX™ is an implant injected into the eye (vitreous) to treat adults with macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

### Important Safety Information

OZURDEX™ should not be used in patients who have any infections or diseases in the eye, or surrounding eye area, including most viral diseases of the cornea and conjunctiva, including active herpes viral infection of the eye, vaccinia, varicella, mycobacterial infections, and fungal diseases.

OZURDEX™ should not be used in patients with advanced glaucoma. You should not use OZURDEX™ if you are allergic to one of its ingredients. Use of corticosteroids may produce posterior subcapsular cataracts, increased eye pressure, glaucoma, and may increase the establishment of secondary ocular infections due to bacteria, fungi, or viruses.

**Please see additional Important Safety Information on pages 12-13.**

# Your treatment:

## OZURDEX™ (dexamethasone intravitreal implant) 0.7mg

### How is OZURDEX™ administered?

The OZURDEX™ implant is so tiny that it can be injected into the eye through a small needle so you won't need surgery to implant OZURDEX™. Each implant is already inside a special applicator device that is needed to perform the insertion. The implant will be injected into the vitreous humor inside your eye. This is known as an intravitreal injection. The next section of this booklet provides more details about the intravitreal injection procedure.

### Will I receive OZURDEX™ more than once?

Your doctor may decide to administer OZURDEX™ again if he or she believes that you may benefit from another injection.



### What results can I expect with an OZURDEX™ intravitreal implant?

It's important to remember that each case of retinal vein occlusion is unique. In clinical studies, 20% (20 of 100) to 30% (30 of 100) patients who received OZURDEX™ gained 3 or more lines of vision on the eye chart in the first 2 months. Once vision had improved, the improvement lasted approximately 1 to 3 months. Your own results may vary.

### Is there anyone who should not be given OZURDEX™?

You should not receive OZURDEX™ if you have an eye infection in or near your eye (including herpes viral infections of the eye; varicella; varicella; mycobacteria; and fungal diseases); if you have advanced glaucoma; or if you are allergic to corticosteroids or to any other ingredient of OZURDEX™ intravitreal implants.

**Please see additional Important Safety Information on pages 12-13.**

A  
*Dexciting*  
Advance

# Your intravitreal injection:

# Understanding the Procedure

## Are intravitreal injections common?

Yes. Intravitreal injections are now used to deliver medication to treat many types of eye conditions. Your Retina Specialist is specially trained in giving eye injections.

## What happens during the injection procedure?

You will be awake during the procedure. Your doctor will follow steps that include ensuring the surface of the eye is clean and numbing the surface of the eye to help keep you comfortable. OZURDEX™ is injected using a special applicator device that's about the size of a pen. The applicator is designed to help your doctor deliver OZURDEX™ to the back of the eye where the medication is needed. The injection will be complete within seconds, and the procedure is generally well tolerated by patients.

## Are there any risks with intravitreal injections?

Injections into the vitreous in the eye have been associated with serious eye infection (endophthalmitis, pronounced en-dof-thal-my-tis), eye inflammation, increased eye pressure, and retinal detachments. In the days following an

injection, patients are at risk for serious eye infection or elevated eye pressure. **If your eye becomes red, sensitive to light, painful, or develops a change in vision, you should seek immediate care from your eye doctor.** Also, you may experience temporary visual blurring after receiving an injection and should not drive or use machines until this has resolved. Your Retina Specialist will discuss the possible risks with you before performing the injection.

## What do patients who've received OZURDEX™ say about their experiences?



“There was  
**no real  
discomfort.**”



“All I felt  
**was a little  
pressure.**”



“I didn't realize he was  
doing the injection  
**until after  
he was done.**”

Not all patients can expect these results.  
*Individual results may vary.*

Please see additional Important Safety Information on pages 12-13.

# Your safety:

# Be Aware and Follow Up

OZURDEX™ is an implant injected into the eye (vitreous) to treat adults with macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

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Injections into the vitreous in the eye are associated with serious eye infection (endophthalmitis), eye inflammation, increased eye pressure, and retinal detachments. In the days following injection with OZURDEX™, patients are at risk for serious eye infection or elevated eye pressure. **If your eye becomes red, sensitive to light, painful, or develops a change in vision, you should seek immediate care from your eye doctor.** You may experience temporary visual blurring after receiving

an injection and should not drive or use machines until this has resolved.

The most common side effects reported in patients include: increased eye pressure, conjunctival bleeding, eye pain, conjunctival hyperemia, ocular hypertension, cataract, vitreous detachment, and headache.

OZURDEX™ is for prescription use only. Individual results with OZURDEX™ may vary.

**Full prescribing information has been provided to your doctor.**

## What else should I know about safety and follow up?

Corticosteroids, such as OZURDEX™ intravitreal implants, can cause the fluid pressure inside the eye to increase. This is not something you can feel. So, following the injection, your doctor should monitor your eye pressure. If you experience this side effect, treatment such as medicated eyedrops may be required to lower the pressure.

Some patients who receive OZURDEX™ intravitreal implants may develop cataracts or their existing cataracts may worsen. It's important to remember that not treating macular edema may lead to irreversible vision loss. You should discuss this issue with your doctor.